

## **II. REMARKS/ARGUMENTS**

Reconsideration and allowance of the subject application are respectfully requested.

Claims 67, 69, 70, 79, 80, 82 and 98-100 are pending in this application, with Claim 67 being the sole independent claim. Claims 67, 70, 79, 82, 98 and 100 have been amended. Claims 1-66, 68, 71-78, 81, 83-97 and 101 have been cancelled without prejudice.

Claim 67 has been amended to include the features of Claim 101. As a result of this amendment, Claim 101 has been cancelled without prejudice or disclaimer, and Claims 70, 82, and 100 have been amended for consistency with Claim 67, to remove reference to the substance being total-Hb or oxy-Hb. The sample set in Claim 67 has also been amended to remove the list of food products, and to remove the reference to the quality control material being stabilized.

Claim 79 has been amended to correct a typographical error. Claim 98 has been amended to indicate that the substances may exhibit one or more negative slopes in the absorbance spectrum. Support for this amendment may be found, for example with reference to Figures 4, 7c, 9, 10, 11a-f, 12a-f, 13a-f and 14a-f, where one or more than one slope is present in the absorbance spectrum of the substance.

### **Rejection under 35 U.S.C. § 112**

Claims 67, 69-70, 73, 79, 80, 82, and 98-101 have been rejected under 35 U.S.C. § 112, on the grounds that the phrase “the quality control material being stabilized” in Claim 67 is indefinite. Applicant has amended Claim 67 to remove this phrase. Claim 101 has been cancelled without prejudice or disclaimer. Therefore the rejection against this claim is moot.

Claim 67 has also been rejected as being indefinite on the grounds that several of the recited samples include food products. Claim 67 has been amended to remove reference to the food products.

Claim 79 has been amended to correct the typographical error identified by the Examiner.

In view of the amendments and remarks set forth above, Applicant respectfully requests that the rejection of Claims 67, 69-70, 73, 79, 80, 82, and 98-101 under 35 U.S.C. § 112 be withdrawn.

#### **Rejections under 35 U.S.C. § 102**

Claims 67, 69-70, 73, 79-80 and 100 are rejected under 35 U.S.C. § 102(b) as being anticipated by Jacobs (either U.S. Patent No. 5,846,492 or 6,013,528). Applicant respectfully traverses this rejection.

Claim 67 is directed to a *quality control material*. A quality control material comprises a composition that may be used to verify or monitor the performance of a calibration algorithm of an apparatus, as stated on page 21, lines 1-3 of the present application. This is in contrast to the *calibrator liquids* disclosed in Jacobs. Calibrator liquids are typically complex mixtures of analytes that are used for the development of calibration algorithms, and not for the verification of the algorithm once it has been developed. In the cited example (Col. 8, lines 26-35, of '528 and Col. 8, lines 48-56, of '492), it is noted that the samples used as calibrator liquids comprise "a human serum matrix" in addition to the spiked components listed in Table 1. These calibrator liquids were then used to "create a calibration algorithm using conventional spectrophotometric practice" as stated in Col. 9, lines 40-43, of '528, or Col. 9, lines 61-63, of

‘492. Calibrator liquids used to develop a primary calibration algorithm typically comprise components that will be found in a sample that is to be measured using the primary calibration algorithm. In the example provided in Jacobs, the calibrator liquids comprised serum and other components that are expected to be in the sample, which is also true for the second set of calibrator liquids described in Jacobs (Col. 10, lines 1-38 of ‘528 or Col. 10, line 32-60 of ‘492). This is in contrast to the quality control materials of the present invention, where the substance within the quality control material mimics an analyte within a sample. In order to further highlight this difference, Claim 67 has been amended to indicate that one or more substances of the quality control material do not mimic themselves, and Claims 70, 82, and 100 have been amended to remove reference to total-Hb and oxy-Hb, so that they are consistent with Claim 67.

The remaining claims all depend ultimately from Claim 67, and include the features of the base claim. Therefore, withdrawal of the rejection of Claims 67, 69-70, 73, 79-80 and 100 under 35 U.S.C. § 102(b) is respectfully requested.


Claims 67, 73, 79 and 100 stand rejected under 35 U.S.C. § 102(e) as being anticipated by Jacobs (U.S. Published Appln. No. 2003/0068822). Applicant respectfully traverses this rejection.

As noted above, Claim 67 has been amended to indicate that the quality control material comprises one or more substances that mimic two or more analytes of a sample and that the one or more substance do not mimic themselves. This combination of elements is not taught in U.S. Published Appln. No. 2003/0068822. Claims 73, 79 and 100 depend from Claim 67 and include the features of Claim 67. Therefore, withdrawal of the rejection against Claims 67, 73, 79 and 100 under 35 U.S.C. § 102(e) is respectfully requested.

It is respectfully submitted that the above-identified application is now in a condition for allowance and favorable reconsideration and prompt allowance of these claims are respectfully requested. Should the Examiner believe that anything further is desirable in order to place the application in better condition for allowance, the Examiner is invited to contact the

Applicant's undersigned attorney by telephone at (202) 625-3500. All correspondence should be directed to our address given below.

Respectfully submitted,

  
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